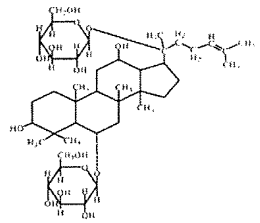
REMARKS

The only issue raised in the official action is whether the invention as claimed in claims 1 -12 is prima facie obvious over a combination of Gai et al Chinese Publication CN 1,273,114 and Su US Patent 4,968,675.

As noted by the Supreme Court in KSR International Co. v. Teleflex, Inc.82 USPQ2d 1385,

> **[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.**

In the present case, the examiner's arguments lack such rational underpinning. Gai teaches production of an injection composition from saponin powder extracted from notoginseng by mixing with "injection water", regulating pH, boiling the solution adding activated carbon, filtering and fine filtering to obtain the product. As noted by the examiner the means for and pH of the pH regulation is not stated. The examiner sees these deficiencies as being solved by Su. However, there is no rational basis for applying Su's teaching to the question of pH regulation in Gai. Su seeks to provide an injectable amino-steroid drug composition that does not cause hemolyis. In particular, this is sought for salts of 16.alpha.-methyl-21-[4-[2,6-bis(1-pyrrolidinyl)-4-pyrimidinyl]-1-piperazin yl]pregna-1,4,9(11)-triene-3,20-dione In order to achieve this, Su turned to teachings relating to Ellipticine (5,11-Dimethyl-6*H*-pyrido[4,3-*b*]carbazole). There is, however, no reason to think that teaching relating to either of these compounds is relevant to saponins obtained from notogiseng. Saponin RG1 referred to in the examples of the present application does not contain nitrogen. It has the formula:



Furthermore, it should be noted that the report on ellipticene included in Su, indicates that the composition described, although avoiding hemolysis, still resulted in hypotension. Su claims the advantage that his composition, which as the examiner notes includes sodium citrate, citric acid and sodium chloride, avoids hypotension and hemolysis when using salts of 16.alpha.-methyl-21-[4-[2,6-bis(1-pyrrolidinyl)-4-pyrimidinyl]-1-piperazin yl]pregna-1,4,9(11)-triene-3,20-dione . However, this does not provide a basis for use of his additive materials for saponins derived from notginseng roots. There is no baisi for thinking that such saponins present the same problems as elliticene and salts of 16.alpha.-methyl-21-[4-[2,6-bis(1-pyrrolidinyl)-4-pyrimidinyl]-1-piperazin yl]pregna-1,4,9(11)-triene-3,20-dione and so no reason to adopt Su's solution. In any case, it is noted that th pH achieved by Su (3.0 - see column 1 line 47) is very different from the pHs shown by the present application to be those to which the present compositions should be adjusted to prevent hydrolysis (about 6 - see the table on page 23). Therefore not only does Su fail to provide information relevant to the present invention, but also if one took the information provided and tried to apply it one would not reach the invention claimed, or indeed any useful product at all.

It is therefore submitted that the invention as claimed meets the requirements of 35

USC 103 and that the application should be allowed. An early action to this end is respectfully solicited.

Respectfully submitted,

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